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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,601	11/21/2003	Jan Markussen	6555.200-US	3120
23650	7590	03/04/2005	EXAMINER	
NOVO NORDISK, INC. PATENT DEPARTMENT 100 COLLEGE ROAD WEST PRINCETON, NJ 08540			ROBINSON, HOPE A	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 03/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/719,601	MARKUSSEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Hope A. Robinson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/29/03, 5/10/04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Notice to comply</u> .                 |

## **DETAILED ACTION**

### ***Application Status***

1. Applicant's election with traverse of Group II (claims 12-21) on December 22, 2004 is acknowledged. Claims 1-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.
2. Applicant's election of Group II in the reply filed on December 22, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Information Disclosure Statement***

3. The Information Disclosure Statements filed on December 29, 2003 and May 10, 2004 have been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

### ***Specification***

4. The specification is objected to because of the following informalities:

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(a) The specification is objected to because trademarks are disclosed throughout the instant specification and not all of them are capitalized or accompanied by the generic terminology. The use of the trademark such as TRIS® for example, has been noted in this application (see page 9, line 17). It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

(b) The specification is objected to because on page 8, line 33, the following typographical error appears, "singl chain insulin", instead of "single chain insulin".

### ***Sequence Compliance***

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825; applicant's attention is directed to the final rule making notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). To be in compliance, applicant is required to identify all amino acid sequences of at least 4 L-amino acids and at least 10 nucleotides by a sequence identifier, i.e., "SEQ ID NO:". The specification discloses sequences that have not been identified by a sequence identifier, see for example, page 8, line 29 (see also claim 21). If these sequences have

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not been disclosed in the computer readable form of the sequence listing and the paper copy thereof, applicant must provide a computer readable form of the "Sequence Listing" including these sequences, a paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable form copies are the same and, where applicable, include no new matter as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d). See the attached Notice to Comply with the sequence rules.

### ***Claim Objection***

6. Claim 12 is objected to because of the following informalities:

Claim 12 is objected to for the recitation of "heating the fermentation broth", instead of "heating a fermentation broth.

Correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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7. Claims 12-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to a process for purifying a fermentation-derived product or a precursor thereof (see for example claims 12 and 19-21) and insulin analogs and insulin analog precursors (claim 21). Dependent claims 13-18 are also included in this rejection because they do not rectify the deficiency. The instant specification does not demonstrate possession of the unspecified amounts of precursors of insulin or all fermentation-derived products or insulin analog precursors to show possession of the claimed genus. Examples 2 and 3 of the instant application do not exemplify a representative number of species (page 10). A representative number of species means that the species, which are adequately described, are representative of the entire genus. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

A search on the patented file database provided 583,340 hits on "human insulin analog", 425,887 hits on "human insulin precursors" and 353,022 hits on "human

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insulin analog precursors. The art also recognizes insulin analogs such as "long acting analogs, somatostatin analogs and basal insulin analogs" for example. Further, a search of the non-patented databases produced 737 insulin analog references. In view of the vast amount of information the instant specification needs to provide adequate written description as to what analogs/precursors are intended in the claimed invention.

On page 4 of the instant specification, it is stated that the precursor means a covalently modified form, which can be converted into the desired form. If the product being produced is, for instance, a protein, then the fermentation-derived product may either be the protein itself or more often a precursor thereof. It is also stated that the precursor can also be the parent protein when the fermentation-derived product is a chemically modified form of the protein. However, the specification does not provide by way of example or description what analogs/precursors are intended. Therefore, the claims lack adequate written description to demonstrate to a skilled artisan that applicant was in possession of the claimed invention as a skilled artisan cannot envision the chemical structure as claimed without a reference structure to be able to determine the claimed analogs or precursors.

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. See *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir.1997). See MPEP 2163.

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Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 18 lacks antecedent basis for "the cut-off value of the UF membrane is lower than about four times the molecular weight of the fermentation-derived product".

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.



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9. Claims 12-21 are rejected under 35 U.S.C. 102(e) as being anticipated by THE GREEN CROSS CORPORATION (EP 699687, June 3, 1996), based on the broad recitation of a purification process involving heating, cooling, separating and isolating any fermentation-derived product or precursor thereof.

GREEN CROSS CORPORATION teach a purification process for recombinant human serum albumin, which involves heating the culture medium containing the rHSA to a temperature range of 50-100 degrees, preferably 60-80 degrees (page 5, lines 34-39). The method step of cooling to a temperature below 60 degrees is inherent by simple logic as the process of GREEN CROSS CORPORATION heats for a specified amount of time (30 minutes), thus will cool to a temperature of below 60 degrees (claim 12) such as about 40 degrees (claim 14) absent heat. In addition, GREEN CROSS CORPORATION teach a separation/isolation process using centrifugation or filtration (claim 15) which would be at a temperature less than 60 degrees as no heat is applied (claim 12), see page 5 of the reference. The GREEN CROSS CORPORATION reference does not teach a flocculation agent (claim 13). The process of ultrafiltration is used in the referenced method (claim 17, page 3, line 13 of GREEN CROSS CORPORATION). GREEN CROSS CORPORATION teach a human serum albumin (claim 20), a protein (claim 19). Therefore, the limitations of the claims are met by this reference.

**Conclusion**

10. No claims are presently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS  
Patent Examiner

*HR*  
*3/3/05*